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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,080	03/15/2004	Jean-Louis Dasseux	9196-031-999	2131

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222 EAST 41ST ST
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,080

Applicant(s)

DASSEUX ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64,65 and 94-127 is/are pending in the application.
- 4a) Of the above claim(s) 64,65,102,105-109 and 111-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94-101, 103-104, 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

NOTE the change of examiner in this application.

1. The amendment and the response filed on 11/15/05 has been fully considered.
2. Claims 63 and 66-93 have been canceled by the amendment filed on 11/15/05.
3. Claims 64-65, 94-127 are currently pending in this application.
4. Applicant's election of Group I (claims 63-118) in the reply filed on 2/4/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
5. Claims 119-127 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
6. Applicant's further election of seq. Id. 4 (PVLDFRELLNELLEALKQKLK: 22 AMINO ACIDS), which is asserted to read on claims 68-101, 103(in part) and 104-110 in the reply filed on 2/4/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
7. Claims 64-65, 102, 105-109 and 111-118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
8. This application contains claims 64, 65, 102, 105-109, and 111-127 drawn to an invention nonelected with traverse in Paper filed on 2/4/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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9. Claims 94-101, 103-104, 110 are currently being examined in this application.

Withdrawn Claim Rejections

10. The new matter rejection of claims 63, 66-93 set forth in the previous office action has been withdrawn in view of cancellation of claims.
11. The written description rejection of claims 63, 66-93 set forth in the previous office action has been withdrawn in view of cancellation of claims.
12. The scope enablement rejection of claims 63, 66-93 set forth in the previous office action has been withdrawn in view of cancellation of claims.
13. The rejection of claim 72 under 35 USC 112, second paragraph, set forth in the previous office action has been withdrawn in view of cancellation of claims.
14. The rejection of claims 63 and 66-86 and 88-93 under 35 U.S.C. 102(a,b,e) as being anticipated by Segrest et al. US Pat. No. 4,643,988, set forth in the previous office action has been withdrawn in view of cancellation of claims.
15. The rejection of claims 63 and 66-93 under 35 U.S.C. 103(a) as being unpatentable over Segrest et al. US Pat. No. 4,643,988 and Isliker et al. US Pat. No. 5,089,602 (2/92), set forth in the previous office action has been withdrawn in view of cancellation of claims.
16. The provisional obviousness-type double patenting rejection of claims 63 and 66-93 over: 10/937,767 (PG PUB: 2005/0080013 A1; 10/801,897 (PG PUB: 2004/0198662A1); 09/865,989 (PG PUB: 2004/0029807 A9); 10/099,574 (PG PUB: 2003/0060604A1); and 09/865,989 (PG PUB: 2003/0008827A1, set forth in the previous office action has been withdrawn in view of cancellation of claims.

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17. The obviousness-type double patenting rejection of claims 63 and 66-93 over: U.S. Patent No. 6,573,239; U.S. Patent No. 6,265,377; U.S. Patent No. 6,046,166; and U.S. Patent No. 6,037,323, set forth in the previous office action has been withdrawn in view of cancellation of claims.

18. The obviousness-type double patenting rejection of claims 94-101, 103-104, 110 over: U.S. Patent No. 6,753,313; 6,716,816; 6,602,854; 6,004,925 and 6,376,464 set forth in the previous office action has been withdrawn in view of filing and entering of terminal disclaimers.

Maintained Claim Rejections

19. The obviousness-type double patenting rejection of claims 94-101, 103-104, 110 over U.S. Pat. No. 6,630,450; U.S. Pat. No. 6,518,412; U.S. Pat. No. 6,329,341, has been maintained for the reasons of record.

20. The provisional obviousness-type double patenting rejection of claims 94-101, 103-104, 110 over claims 1-68 of copending Application No. 10/283,599 (PG PUB. 2003/0208059A1); ii. claims 1-56 of copending Application No. 10/099,836 (PG PUB 2003/0203842A1) has been maintained for the reasons of record.

Response to Arguments

21. *Claims 63, 66-101, 103-104 and 110 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:*

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- i. claims 1-68 of copending Application No. 10/283,599 (PG PUB. 2003/0208059A1);*
- ii. claims 1-56 of copending Application No. 10/099,836 (PG PUB 2003/0203842A1).*

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the above-cited applications teach pharmaceutical compositions comprising ApoA-I agonist peptide compounds (INCLUDING ELECTED SPECIES OF SEQ. ID : 4) comprising 15-29 residues comprising charged residues (e.g. 3-5) and hydrophobic residues (e.g. 40-70%) within the scope of the presently claimed invention which further form an amphipathic helix in the presence of lipids (e.g. an "ApoA-I agonist "discoidal" lipid complex) with @ 38% which form LCAT activation.

Regarding limitations if not explicitly taught by the application claims e.g.:

- a. the degree of helicity of peptide/lipid complex (e.g. 40-80%: claims 68-69);*
- b. mean hydrophobic moment/hydrophobicity (e.g. claims 78-83); and*
- c. phi angle (e.g. 60 degrees to 220 degrees : claim 84-85)*
- d. proportion of lipid/peptide (e.g. claims 92-93)*

it is noted that the application claim peptides are clearly within the presently claimed scope of chemical structure and/or clearly represent ApoA-I agonist compounds sharing amino acid composition and /or lipid complexing to form helices and LCAT activation; and contain hydrophobic amino acids and thus should be expected to possess mean hydrophobic moments/hydrophobicity and possess phi angles within the scope of the presently claimed invention as discussed above. Alternatively, the above cited items a-d not explicitly taught by the reference would nevertheless be deemed to be inherently present absent evidence to the contrary. In this regard it is noted that the PTO lacks facilities for comparing prior art compounds to

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compounds within the broad scope of the presently claimed invention; thus shifting the burden to applicant to provide otherwise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Applicant's arguments filed on 11/15/05 have been fully considered but they are not persuasive.

Regarding the provisional ODP rejection over 10/099,836, applicants have requested that the rejection be held in abeyance until either the application is allowed. Applicants request has been considered, and the rejection of record is maintained.

Regarding the rejection over 10/283,599 (US Patent 6,844,327), applicants argue that the rejection is moot regarding canceled claims 63, 66-93; and applicants traversed the rejection regarding claims 94-101, 103-104 and 110. Applicants argue that the '327 patent claims recite nucleotide sequence that encode ApoA-I agonist peptide compounds; and the claims are patentably distinct from claims 94-101, 103-104 and 110 of the instant application. Thus, the double patenting rejection is improper and should be withdrawn.

Applicant's arguments have been fully considered and are not persuasive. The reference claims recite nucleic acid sequence encoding SEQ ID NO: 4, and the SEQ ID NO: 4 is ApoA-I agonist used in the pharmaceutical composition of the instant claims. Thus, the reference claim nucleic acid encodes the ApoA-I of the instant claimed composition. In this instance the examiner has not relied on the specification to interpret the claims, thus contradicts the General Foods Corp case. And further, the instant claims were not restricted in the '357 patent

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application, such that prohibition against double patenting rejection under 35 USC. 121 does not apply. And for the reasons of record the rejection has been maintained.

23. *Claims 63,66-101, 103-104 and 110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:*

- i. claims 1-48 of U.S. Pat. No. 6,753,313;*
- ii. claims 1-58 of U.S. Pat. No. 6,716,816;*
- iii. claims 1-36 of U.S. Pat. No. 6,630,450;*
- iv. claims 1-38 of U. S. Pat. No. 6,602,854;*
- v. claims 1-9 of U.S. Pat. No. 6,518,412;*
- vi. claims 1-21 of U.S. Pat. No. 6,376,464;*
- vii. claims 1-21 of U.S. Pat. No. 6,329,341; and*
- viii. claims 1-58 of U.S. Pat. No. 6,004,925.*

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the above-cited patents teach pharmaceutical compositions comprising Apo-A1 agonist peptide compounds (INCLUDING ELECTED SPECIES OF SEQ. ID : 4) comprising 15-29 residues comprising charged residues (e.g. 3-5) and hydrophobic residues (e.g. 40-70%) within the scope of the presently claimed invention which further form an amphipathic helix in the presence of lipids (e.g. an "ApoA-I agonist "discoidal" lipid complex) with @ 38% which form LCAT activation.

Regarding limitations if not explicitly taught by the application claims e.g.:

- a. the degree of helicity of peptide/lipid complex (e.g. 40-80%: claims 68-69);*

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b. mean hydrophobic moment/hydrophobicity (e.g. claims 78-83); and

c. phi angle (e.g. 60 degrees to 220 degrees : claim 84-85)

d. proportion of lipid/peptide (e.g. claims 92-93)

it is noted that the application claim peptides are clearly within the presently claimed scope of chemical structure and/or clearly represent ApoA-I agonist compounds sharing amino acid composition and /or lipid complexing to form helices and LCAT activation; and contain hydrophobic amino acids and thus should be expected to possess mean hydrophobic moments/hydrophobicity and possess phi angles within the scope of the presently claimed invention as discussed above. Alternatively, the above cited items a-d not explicitly taught by the reference would nevertheless be deemed to be inherently present absent evidence to the contrary. In this regard it is noted that the PTO lacks facilities for comparing prior art compounds to compounds within the broad scope of the presently claimed invention; thus shifting the burden to applicant to provide otherwise.

24. Applicant's arguments filed on 11/15/05 regarding the ODP rejections of claims over US Patents 6,630,450; 6,329,341 and 6,518,412, have been fully considered but they are not persuasive.

Applicants traverse the ODP rejection over claims of US Patent 6,630,450. Applicants argue that the reference claims ('450 claims) are drawn to method of treating a disorder using apolipoprotein A-I peptide or analogs; and the instant claims are drawn to ApoA-I-lipid complex. Applicant's arguments have been fully considered and are not persuasive, since the reference claimed method uses the same ApoA-I protein and pharmaceutical salt thereof. And further the

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reference clearly recites that the peptide or the peptide analog forms an amphipathic alpha-helix in presence of lipid. And the reference claims 20-21 specifically recite that ApoA-I agonist compound in the form of pharmaceutical composition comprising ApoA-I peptide and pharmaceutically acceptable carrier and lipid. And claims 22-23 recite the specific lipid. Thus, applicant's arguments are not persuasive and the General Foods Corp case is not applicable to the instant claims. The rejection of record has been maintained over the claims US Patent 6,630,450.

Applicants traverse the ODP rejection over claims of US Patent 6,518,412. Applicants argue that the reference claims are drawn to nucleic acid and the instant claims are drawn to pharmaceutical composition. Since the reference claims recite nucleic acid encoding the same exact ApoA-I peptide of the instant claims; and no restriction was made in the either in the '412 patent application or in the instant application, the ODP rejection is proper. And the ruling of the General Foods Corp case is not applicable, since the reference claims clearly recite the nucleic acid encoding the peptides of the instant claims. Thus, the ODP rejection over the claims of US Patent 6,518,412 has been maintained.

Applicants traverse the ODP rejection over claims of US Patent 6,329,341. Applicants argue that the reference claims ('341 claims) are drawn to method of treating septic sock using apolipoprotein A-I peptide or analogs; and the instant claims are drawn to pharmaceutical composition of ApoA-I-lipid complex. Applicant's arguments have been fully considered and are not persuasive, since the reference claimed method uses the same ApoA-I protein agonist and pharmaceutical salt thereof. And further the reference clearly recites that the peptide or the peptide analog forms an amphipathic alpha-helix in presence of lipid. And the specification

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discloses that 'ApoA-I agonists are formulated as peptides or peptide-lipid complexes (i.e., see column 47); and in column 50 as pharmaceutical formulations; and the preferred embodiment of the invention is 'administering the ApoA-I agonist as a complex with spingomyelin (see column 49). Applicants arguments regarding the General Foods Corp case is not applicable to the instant claims, because the examiner has relied on the specification disclosure to learn the meaning of a term Apo-A-agonist in the reference claims.

*The specification can * be used as a dictionary to learn the meaning of a term in the patent claim. **> Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999) Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970) (See MPEP 804).*

Thus, for the reasons of record the rejections have been maintained.

Conclusion

25. No claims are allowed.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

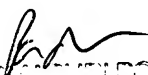
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

15 February 2006


PADMINI PONNALURI
PRIMARY EXAMINER